



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,495	10/20/2003	Rui Sousa	310307.90240	4308

26735 7590 06/05/2006

QUARLES & BRADY LLP
FIRSTAR PLAZA, ONE SOUTH PINCKNEY STREET
P.O BOX 2113 SUITE 600
MADISON, WI 53701-2113

EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/689,495	Applicant(s) SOUSA, RUI	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 25, 28, and 38, drawn to a method of synthesizing a nucleic acid molecule, classified in class 435, subclass 6. If elected, this Group is subject to further species requirement.
- II. Claims 13-16, 29, 32, 33, 36, 37, 39, and 40, drawn to a kit, classified in class 530, subclass 183. If elected, this Group is subject to further species requirement.
- III. Claims 17-24, 26, 27, 30, 31, 34, and 35 drawn to a method of determining the sequence of a nucleic acid, classified in class 435, subclass 6. If elected, this Group is subject to further species requirement.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions employ different elements and modes of operation to achieve different outcomes. For example, a method of sequencing nucleic acid molecules involving promoter and/or primers, as well as dideoxynucleotides are not required of the method synthesizing a nucleic acid molecule which could be for any purposes, such as making antisense molecule, the embodiment of which is clearly contemplated by the instant application (see claim 11).

Invention II is related to Inventions I and III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

Art Unit: 1637

as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the kit of Group II can be used in either of the methods of Groups I and III. In addition, Applicants are advised that the kit claims, while dependent on different method claims, comprise the same element; and since a kit is defined by the elements comprised in said kit, all kit claims have been grouped together in a single Group. However, should Applicants elect and amend the kit claims to comprise different elements, further restriction, necessitated by the Amendment, would result.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further Species Requirement

Group I:

This application contains claims directed to the following patentably distinct species: claim 8 recites a Markush group of patentably distinct T7-type RNA polymerases. These species are independent or distinct because they have different amino acid sequences and different structures.

The species are as follows:

- a) T7 RNA polymerase;
- b) T3 RNA polymerase; and
- c) SP6 RNA polymerase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-7, 9-12, 25, 28, and 38 are generic.

Art Unit: 1637

Group II:

This application contains claims directed to the following patentably distinct species: the claims are drawn to a kit comprising a double mutant polymerase which comprises two different types of double mutations, which are mutually exclusive of each other. These species are independent or distinct because they have mutually different double mutations which are responsible for the observed, reduced discrimination between canonical and non-canonical nucleoside triphosphates.

The species are as follows:

- a) altered amino acid at positions 639 and 784 (claim 15); and
- b) altered amino acid at positions 631 and 779 (claim 16).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 13, 14, 29, 32, 33, 36, 37, 39, and 40 are generic.

Group III:

This application contains claims directed to the following patentably distinct species: the claims are drawn to a two distinct methods of nucleic acid sequencing – *de novo*, which does not require primer mediation; and primer-mediated. These species are independent or distinct because they are not capable of being performed together, requiring different modes of operation (one requires a promoter sequence and without a primer while the other does not require a promoter, but a primer).

The species are as follows:

- a) *de novo* nucleic acid sequencing (claims 17-20, 26, 27, 30, and 31); and
- b) primer-assisted nucleic acid sequencing (claims 21-24, 34, and 35)

Art Unit: 1637

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, no claim is generic.

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

Art Unit: 1637

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Inquiries

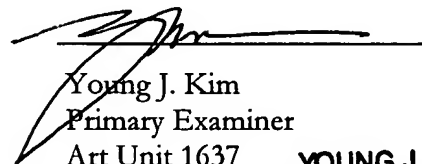
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the

Art Unit: 1637

status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim

Primary Examiner

Art Unit 1637

5/30/2006

**YOUNG J. KIM
PATENT EXAMINER**

yjk